

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

SERGEANTS BENEVOLENT
ASSOCIATION HEALTH & WELFARE
FUND, on behalf of itself and all others
similarly situated,

Plaintiff,
vs.

FOUGERA PHARMACEUTICALS, INC.,
HI-TECH PHARMACAL CO., INC.,
PERRIGO COMPANY PLC, SANDOZ, INC.,
TARO PHARMACEUTICAL INDUSTRIES,
LTD., TARO PHARMACEUTICALS USA,
INC., and WOCKHARDT USA LLC,

Defendants.

Case No. _____

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiff Sergeants Benevolent Association Health & Welfare Fund, on behalf of itself and all others similarly situated, files this Class Action Complaint against Defendants Fougera Pharmaceuticals Inc. (“Fougera”), Hi-Tech Pharmacal Co., Inc. (“Hi-Tech”), Perrigo Company PLC (“Perrigo”), Sandoz, Inc. (“Sandoz”), Taro Pharmaceutical Industries Ltd (“Taro Israel”), Taro Pharmaceuticals USA, Inc. (“Taro U.S.A.”),¹ and Wockhardt USA LLC (“Wockhardt”) and alleges as follows based on: (a) personal knowledge; (b) the investigation of its counsel; and (c) information and belief.

I. NATURE OF THE ACTION

1. This is a civil antitrust action brought by Plaintiff on behalf of a proposed class of end-payors who indirectly purchased, reimbursed, or otherwise paid for the following formulations of generic Clobetasol Propionate: (1) topical ointment .05%; (2) topical solution

¹ Taro Israel and Taro U.S.A. are collectively referred to as “Taro.”

.05%; (3) topical gel .05%; or (4) topical cream .05% (collectively “Clobetasol”). Clobetasol—one of the most prescribed dermatological drugs in the United States—is a topical corticosteroid used for the treatment of a variety of skin conditions, including eczema, dermatitis, psoriasis, and vitiligo. Plaintiff seeks overcharge damages and other relief arising out of Defendants’ agreement not to compete in the market for generic Clobetasol.

2. Since June 2014, Defendants Fougera, Hi-Tech, Perrigo, Taro, and Wockhardt have been the primary manufacturers of generic Clobetasol available for purchase in the United States. Defendant Sandoz acquired Fougera in 2012.

3. For 2014, Clobetasol was among the four generic drugs that experienced the largest price increases across the United States generic pharmaceutical industry. Starting in June 2014, immediately following a meeting of generic pharmaceutical manufacturers attended by Hi-Tech, Perrigo, Sandoz, Taro U.S.A., and Wockhardt, Defendants began dramatically raising the price of generic Clobetasol. Between June and September 2014, Defendants collectively raised their Clobetasol prices approximately 1,140%. Defendants’ Clobetasol prices have stabilized at supracompetitively high levels. Between August 2014 and August 2015, Defendants collectively maintained Clobetasol price increases of approximately 950%. Whereas, in 2013, a 60-gram tube of Clobetasol cream cost \$15.60, as of 2015, the cost was nearly \$250.

4. Defendants’ dramatic price hikes were, for the most part, in lockstep. Between August 2014 and August 2015, for example, Taro U.S.A., Hi-Tech, and Fougera each raised the price per unit for generic Clobetasol topical ointment 1,263.51%. The price increases of other formulations were likewise often identical among manufacturers. As of August 2016, the price of Clobetasol remains approximately 800% higher than early 2014 levels.

5. Such dramatic increases are not the product of a competitive market, and were not made necessary by increased manufacturing costs. And because generic pharmaceutical manufacturers do not need to incur the large research and development costs that brand manufacturers absorb in developing new drugs, the price increases cannot be attributed to the need to fund research and development.

6. Defendants' price hikes occurred at a time during which congress and regulators are focusing intense scrutiny on generic manufacturers' anticompetitive pricing practices. In December 2015, in response to a congressional request to examine generic drug price increases, the Office of Inspector General of the United States Department of Health and Human Services concluded price increases in 22 percent of the top 200 generic drugs exceeded the cost of inflation. Such increases, particularly when they are the product of a coordinated decision not to compete, contravene the basis for generic drugs' existence—to provide the public with access to needed, therapeutically equivalent pharmaceuticals at more affordable prices than are available for brand name prescription drugs.

7. On September 9, 2016, Taro Israel disclosed that the United States Department of Justice issued subpoenas to Taro U.S.A. and two of its senior officers relating to its ongoing investigation of anticompetitive practices in the generic pharmaceutical industry. The DOJ's subpoenas follow a number of press reports that highlighted concerns about the rising prices of generic Clobetasol.

8. Defendants' coordinated decision not to compete was designed to and did fix, raise, maintain, or stabilize the price of generic Clobetasol. As a result, Defendants violated (1) sections 1 and 3 of the Sherman Act, 15 U.S.C. §§ 1, 3; and (2) the various state antitrust and consumer protection laws enumerated below. Plaintiff seeks the damages it sustained and

injunctive relief to prevent Defendants from continuing and maintaining the anticompetitive combination, conspiracy, or agreement alleged in this complaint.

II. JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and 15 U.S.C. sections 1, 3 and 26. This Court has subject matter jurisdiction over the state law claims pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. sections 1332(d) and 1367, in that this is a class action in which the members of the Class (as defined herein) exceed 100; the matter in controversy exceeds the sum of \$5,000,000, exclusive of interest and costs; and at least one member of the Class is a citizen of a state different from that of one of the Defendants.

10. Jurisdiction and venue are proper in this Court under 28 U.S.C. section 1391 because Defendants transact business in this District and Defendant Taro U.S.A.'s principal place of business is in this District. A substantial part of the interstate trade and commerce involved and affected by the violations of the antitrust laws was and is carried on in part within this District. The acts complained of have and will continue to have substantial effects in this District.

III. PARTIES

A. Plaintiff

11. Sergeants Benevolent Association Health & Welfare Fund ("SBA Fund") is located in New York and was established for the purpose of providing benefits to approximately 4,700 active and 7,600 retired New York City Police Department Sergeants and their dependents. As a third-party payor of pharmaceutical claims for its members, the SBA Fund is the indirect purchaser of Clobetasol and was thereby injured as a result of Defendants' unlawful behavior.

The SBA Fund has purchased and/or provided reimbursement for generic Clobetasol claims throughout the country since June 3, 2014, including in Florida, Georgia, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, South Dakota, and Virginia.

B. Defendants

12. Defendant Fougera Pharmaceuticals, Inc. is a New York corporation with its principal place of business in Melville, New York. Fougera markets and sells generic Clobetasol throughout the United States.

13. Defendant Sandoz, Inc.—a Colorado corporation with a principal place of business in Princeton, New Jersey—is the United States affiliate of Sandoz International GmbH, a company organized and existing under the laws of Germany, having its principal place of business in Holzkirchen, Germany. Sandoz, Inc. is responsible for the distribution of drugs developed and manufactured by Sandoz International. In tandem, Sandoz International and Sandoz, Inc. operate as the generic pharmaceuticals division of Novartis International AG, a global healthcare company based in Switzerland. In 2012, Novartis acquired Fougera for approximately \$1.5 billion.

14. Defendant Hi-Tech Pharmacal Co., Inc. is a Delaware Corporation with its principle place of business in Amityville, New York. Hi-Tech markets and sells generic Clobetasol throughout the United States. Akorn, Inc., a pharmaceutical company focusing on the marketing and sale of generic and branded prescription drugs, acquired Hi-Tech in April 2014 for \$640 million.

15. Defendant Perrigo Company PLC is incorporated under the laws of Ireland with its principal place of business in Dublin, Ireland. Perrigo markets and sells generic Clobetasol throughout the United States.

16. Defendant Taro Pharmaceuticals USA, Inc. is a New York corporation with its principal place of business in Hawthorne, New York. Taro markets and sells generic Clobetasol throughout the United States. Taro U.S.A. is a wholly-owned subsidiary of Defendant Taro Pharmaceutical Industries Ltd., an Israeli company with its principal place of business in Haifa, Israel.

17. Defendant Wockhardt USA LLC is a Delaware corporation with its principal place of business in Parsippany, New Jersey. Wockhardt markets and sells generic Clobetasol throughout the United States.

IV. CO-CONSPIRATORS AND AGENTS

18. The anticompetitive and unlawful acts alleged against the Defendants in this complaint were authorized, ordered or performed by Defendants and their respective directors, officers, agents, employees, or representatives, while actively engaged in the management, direction, or control of Defendants' business or affairs.

19. Various persons and/or firms not named as Defendants may have participated as co-conspirators in the violations alleged in this complaint and may have performed acts and made statements in furtherance of such violations.

20. Each Defendant acted as the principal, agent or joint venturer of, or for, other Defendants with respect to the acts, violations, and common course of conduct alleged in this complaint.

21. The agency relationships formed among the Defendants with respect to the acts, violations, and common course of conduct alleged in this complaint were consensually formed between the Defendant principals and agents. Defendants' agents acted in the United States and abroad within the scope of their agency relationship with their own principals. Defendants'

agents acted under the explicit authority, implied authority or apparent authority of their principals. These acts include subsidiaries selling, distributing, or shipping generic Clobetasol at the request of their parent companies. Further, Defendants acted on behalf of and were subject to the control of their principals, and they acted within the scope of authority or power delegated by their principals. Defendants' agents performed their duties with appropriate care and diligence, within the scope of their agency, in selling, distributing, or shipping generic Clobetasol that had been sold at supracompetitive prices.

22. Accordingly, the Defendant principals are liable for the acts of their agents. Likewise, the Defendant agents are liable for the acts of their principals conducted by the agents within the scope of their explicit, implied or apparent authority.

V. CLASS ACTION ALLEGATIONS

23. Plaintiff brings this action on behalf of itself and, under Federal Rules of Civil Procedure 23(a), (b)(2) and (b)(3), as representatives of a Class defined as follows:

All persons or entities

- (1) in the United States, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for generic Clobetasol Propionate: (1) topical ointment .05%; (2) topical solution .05%; (3) topical gel .05%; or (4) topical cream .05% manufactured by Defendants and/or their affiliates in Alabama, Arizona, California, the District of Columbia, Florida, Guam, Hawaii, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin, and/or
- (2) who reside in Alabama, Arizona, California, the District of Columbia, Florida, Guam, Hawaii, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin and indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for generic Clobetasol Propionate: (1) topical ointment .05%; (2) topical solution

.05%; (3) topical gel .05%; or (4) topical cream .05% manufactured by Defendants and/or their affiliates in the United States, the District of Colombia, or Puerto Rico

for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the “Class”), other than for resale at any time during the period June 3, 2014, through the date the anticompetitive effects of Defendants’ challenged conduct cease (the “Class Period”).

24. The following persons or entities are excluded from the Class:

- Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;
- All federal or state governmental entities, excluding cities, towns, or municipalities with self-funded prescription drug plans;
- All persons or entities who purchased generic Clobetasol for purposes of resale directly from Defendants and their affiliates;
- Fully insured health plans, *i.e.*, plans that purchased insurance from another third-party payor covering 100% of the plan’s reimbursement obligations to its members;
- Any “flat co-pay” consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;
- Pharmacy Benefits Managers; and
- The judges in this case and any members of their immediate families.

25. Class members are so numerous that joinder is impracticable. Members of the Class are widely dispersed throughout the country. Plaintiff believes the Class includes hundreds of thousands, if not millions, of consumers and thousands of third-party payors.

26. Plaintiff’s claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, they paid artificially inflated prices for generic Clobetasol, and were deprived of the benefits of competition as a result of Defendants’ wrongful conduct.

27. Plaintiff will fairly and adequately protect and represent the interests of the Class.

Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

28. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular expertise with class action antitrust litigation in the pharmaceutical industry.

29. Questions of law and fact common to the members of the Class predominate over any questions that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class.

30. Questions of law and fact common to the Class include:

- whether Defendants violated sections 1 and 3 of the Sherman Act, 15 U.S.C. §§ 1 and 3;
- whether Defendants' combination, conspiracy, or agreement, alleged herein constitutes a violation of the state laws listed below;
- whether Defendants conspired to and did suppress competition in the market for generic Clobetasol;
- whether Defendants' challenged conduct harmed competition in the generic Clobetasol market;
- whether, and to what extent, Defendants' conduct as alleged herein caused antitrust injury to the business or property of Plaintiff and the members of the Class in the nature of overcharges;
- the quantum of aggregate overcharge damages paid by the class; and
- whether Plaintiff and Class members are entitled to injunctive relief to prevent further violation of sections 1 and 3 of the Sherman Act.

31. Class treatment is a superior method for the fair and efficient adjudication of the controversy, because, among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a similar forum simultaneously, efficiently and without the unnecessary duplication of evidence, effort and expense that numerous

individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in the management of this class action.

32. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

VI. INTERSTATE AND INTRASTATE COMMERCE

33. At all material times, Defendants, directly or through one or more of their respective parents, subsidiaries, business units, agents or affiliates, promoted, distributed, sold or delivered substantial amounts of generic Clobetasol in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

34. At all material times, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of generic Clobetasol.

35. Defendants engaged in conduct both inside and outside of the United States that caused direct, substantial, and reasonably foreseeable and intended anticompetitive effects upon interstate commerce within the United States.

36. Generic Clobetasol manufactured abroad by the Defendants or their affiliates and sold in the United States constitutes domestic or import commerce.

37. In furtherance of their efforts to restrain competition in the market for generic Clobetasol, Defendants employed the United States and interstate and international telephone

lines, as well as means of interstate and/or international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

38. Defendants' anticompetitive conduct has had substantial intrastate effects in that, among other things, retailers within each state did not have access to less expensive generic Clobetasol that they could sell to end-payors within each respective state. Defendants' anticompetitive combination, conspiracy or agreement to reduce competition in the market for generic Clobetasol has directly impacted and disrupted commerce for end-payors within each state.

39. During the relevant time period, generic Clobetasol was shipped into each state and was sold to or paid for by end-payors.

40. Defendants' conduct as alleged herein has had substantial effects on intrastate commerce in each state because generic Clobetasol was sold to consumers and third-party payors in each state and Defendants entered into an unlawful, anticompetitive agreement that affected commerce in each state.

VII. FACTUAL ALLEGATIONS

A. Differences Between Branded and Generic Drugs

41. Bringing a new drug to market is costly. Accordingly, subject to certain conditions, pharmaceutical manufacturers who invest in research and development and successfully develop and bring to market a new drug are afforded a finite period of exclusivity during which they can market and sell the new drug at higher prices without the threat of competitors offering the same product at lower prices. The exclusivity period is designed to promote a balance between new drug innovation and generic drug competition.

42. Under the Federal Food, Drug, and Cosmetic Act, a manufacturer who creates a new drug product must obtain the approval of the Food and Drug Administration (“FDA”) to sell the new drug by filing a New Drug Application (“NDA”). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning safety and effectiveness, among other things. 21. U.S.C. § 355(a), (b). NDAs that meet certain requirements are eligible for exclusivities that prevent the FDA from approving applications for the same drug for prescribed periods of time.

43. Once the FDA approves a brand manufacturer’s NDA, the brand manufacturer may list the patents identified by the brand manufacturer in “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.” In the United States it takes an average of over 10 years to bring a new drug to market.

44. The process for bringing a generic drug to market is simpler and cheaper. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A generic manufacturer seeking approval to sell a generic version of a brand drug may instead file an abbreviated new drug application or “ANDA.” An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer’s original NDA, and must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is therapeutically equivalent to the brand drug.

45. Generic drugs that are therapeutically equivalent to their brand drugs are given an “AB” rating by the FDA, allowing their substitution for the brand product when an end-payor presents a prescription for the brand drug.

46. As part of the FDA’s ANDA approval process, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book by asserting one of four certifications: (1) no patent for the brand drug has been filed with the FDA; (2) the patent for the brand drug has expired; (3) the patent for the brand drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or (4) the patent for the brand drug is invalid or will not be infringed by the generic manufacturer’s proposed product.

47. Under the Hatch-Waxman Act, the first company to submit a substantially complete ANDA with the FDA has the exclusive right to market the generic drug for 180 days.

48. Congress enacted the Hatch-Waxman Amendments to expedite the entry of generic competitors, reducing healthcare expenses across the country. Generic drug products play a critical role in the United States pharmaceutical market because they are the only form of direct economic and price competition from identical, therapeutically equivalent drug products which can be substituted legally for brand name drugs. Generic drugs can serve the function of lowering prices through competition effectively only through the substitution of AB-rated drugs. Absent the ability of purchasers to choose an AB-rated therapeutically equivalent generic alternative, brand drugs face little to no competition. The prevalence of AB-rated generic drugs thus helps to ensure that a competitive market for drug products exists.

49. In short, the lower-cost, expedited approval process and exclusivity provisions provided under Hatch-Waxman were designed to provide consumers with faster, cheaper access

to bioequivalent generics while still encouraging innovation in new drug development. Thus, the expected price pattern for a generic entrant under normal circumstances is that it enters the market at a price 10% to 25% lower than the brand name price and the price quickly and continually declines as other generic products enter the market until a market leveling price is reached.

B. Consolidation of the Generic Drug Market

50. The global market for generic pharmaceuticals has undergone substantial consolidation since 2005. Generic pharmaceutical industry leader Teva Pharmaceutical Industries Ltd., for example, acquired Ivax Corporation for \$7.4 billion in 2006, Barr Laboratories for \$7.4 billion in 2008, Ratiopharm—Germany’s second largest generic drug producer—for \$5 billion in 2010; and agreed to acquire Allergan Generics in 2015 for \$40.5 billion. Other major transactions that occurred during the same time period include Watson Pharmaceuticals’ \$1.9 billion acquisition of Andrx Corporation in 2006; Daiichi Sankyo’s purchase of a majority stake in Ranbaxy in 2008; and Endo Pharmaceuticals’ 2010 acquisition of Qualitest for \$1.2 billion.

51. Similar consolidation has occurred in the market for generic Clobetasol. In the years leading up to Defendants’ price increases, generic manufacturers Glenmark Pharmaceuticals and Teva Pharmaceutical Industries left the Clobetasol market, leaving Defendants with near complete control over product supply. In 2009, there were approximately ten manufacturers of generic Clobetasol Propionate topical ointment .05%, topical solution .05%, topical gel .05%, and topical cream .05%. As of 2014, about half as many manufacturers remained.

52. The result of the generic drug industry's consolidation has been higher prices for consumers. Generic manufacturers merged as a partial reaction to the consolidation of the distributors, the logic being that generic manufacturers could exert leverage to charge higher prices if distributors were stripped of the option of negotiating lower prices with other generic manufacturers offering therapeutically equivalent drugs. Market consolidation has also resulted in more generic product lines being combined or discontinued, further reducing price competition.

C. Clobetasol Price Increases

53. Clobetasol is a high strength topical corticosteroid used to treat a wide variety of skin conditions, including eczema, psoriasis, sebderm, dermatitis, and vitiligo. Clobetasol is one of the most widely used dermatological drugs. While it is intended to be used temporarily due to its potency it can be used for longer periods of time in certain cases. Of the formulations at issue in this case—ointment, solution, gel, and cream—ointment is the most commonly used.

54. In 2014, Defendants caused the price of Clobetasol to dramatically increase over a period of just 12 weeks by entering into an anticompetitive agreement to restrain competition.

55. Defendants Hi-Tech, Perrigo, Sandoz, Taro U.S.A., and Wockhardt each attended the Generic Pharmaceutical Association's (GPhA's) annual meeting in North Bethesda Maryland on June 3 and June 4, 2014. The GPhA describes itself as "the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry." The GPhA was formed in 2000, after the merger of three other generic drug trade associations—the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical

Manufacturers, and the National Pharmaceutical Alliance. The meeting provided Defendants with opportunities to collude.²

56. National Average Drug Acquisition Cost (“NADAC”) data³ demonstrates that shortly following the meeting, the cost of generic Clobetasol underwent a dramatic, across-the-board increase. Between June and September 2014, Defendants increased their prices for generic Clobetasol approximately 1,140%.

57. Defendants have maintained their anticompetitively inflated prices. Between August 2014 and August 2015, Defendants increased the prices for all products at issue an average of 946.86%, with certain products increasing as much as 1,270.01%. In most cases, Defendants implemented identical per-unit price increases. As of August 2016, the cost of generic Clobetasol remains inflated 772.4% higher than prior to the June 2014 generic pharmaceutical trade association meeting.

58. The following tables demonstrate the average NADAC cost increases for each Clobetasol product at issue in this complaint. Table 1 shows the average price increases carried out by each Defendant at the product level from August 2014 to August 2015. Table 2 shows the average price increases from August 2014 to August 2016, establishing that the price Defendants are charging for generic Clobetasol has stabilized at anticompetitively high levels.

² Defendants Perrigo and Sandoz sit on the GPhA’s board of directors.

³ NADAC is a measure of the cost of drugs developed by the National Association of State Medicaid Directors to set a single national pricing benchmark based on average drug acquisition costs.

Table 1
(Percent Increase Per-Unit Between 2014 and 2015)⁴

Manufacturer	Topical Ointment	Topical Solution	Topical Gel	Topical Cream	Topical Cream (Emollient) / Embeline E	All Formulations
Fougera	1,263.51%	1,142.66%	894.35%	1,270.01%	688.92%	1,051.89%
Hi-Tech	1,263.51%	815.25%	894.35%	1,270.01%	688.92%	986.41%
Perrigo	X	X	894.35%	X	X	894.35%
Taro	1,263.51%	815.25%	894.35%	1,270.01%	688.92%	986.41%
Wockhardt	X	815.25%	X	X	X	815.25%
Total	1263.51%	897.10%	894.35%	1,270.01%	688.92%	946.86%

Table 2
(Percent Increase Per-Unit Between 2014 and 2016)

Manufacturer	Topical Ointment	Topical Solution	Topical Gel	Topical Cream	Topical Cream (Emollient) / Embeline E	All Formulations
Fougera	1,063.03%	831.68%	869.30%	810.12%	615.99%	838.02%
Hi-Tech	1,063.03%	605.28%	869.30%	810.12%	615.99%	792.74%
Perrigo	X	X	869.30%	X	X	869.30%

⁴ Entries marked by an “X” reflect instances where a manufacturer did not produce a certain formulation of generic Clobetasol.

Taro	1,063.03%	605.28%	869.30%	810.12%	615.99%	792.74%
Wockhardt	X	605.28%	X	X	X	605.28%
Total	1,063.03%	661.88%	869.30%	810.12%	615.99%	779.62%

59. Defendants' price increases were not necessitated by increased manufacturing costs. They were likewise not necessarily incurred to defray the cost to bring Clobetasol to market, which Defendants—manufacturers of generic, not branded Clobetasol—did not incur in connection with the at-issue products. Accordingly, through their anticompetitive agreement to fix, increase, and maintain the price of generic Clobetasol, Defendants were able to substantially increase their revenues without having made investments in research, development, or other costs associated with bringing brand name Clobetasol to market.

D. Factors Corroborating Defendants' Price-Fixing Agreement

60. In addition to the pricing data set forth above, several market and other relevant factors give rise to a reasonable inference that Defendants acted unlawfully and in concert to raise and fix Clobetasol prices far above competitive levels. Since at least June 3, 2014, the United States market for generic Clobetasol has been characterized by numerous factors that facilitated Defendants' conspiracy, including: (1) market concentration among a limited number of participants; (2) high barriers to entry; (3) mutual interchangeability of Defendants' products; (4) inelasticity of demand; (5) the lack of available substitutes for the products involved; (6) absence of a competitive group of sellers; and (7) ease of information sharing among Defendants.

1. Market Concentration

61. Where a market is concentrated among a small number of firms, it is easier for those firms to collude. As is described at paragraphs 50 - 52, the generic Clobetasol market has undergone substantial consolidation in recent years.

62. Defendants control nearly all of the market for generic Clobetasol topical ointment .05%; topical solution .05%; topical gel .05%; and topical cream .05%.

63. In the United States, the sales of generic Clobetasol remain large—for 2015 generic Clobetasol was one of the two most utilized drugs for skin conditions.

64. Given the lack of competing manufacturers of generic Clobetasol, the Defendants' concerted actions have had the ability to, and did, impact pricing and output in the United States.

2. High Barriers to Entry

65. Markets are more susceptible to anticompetitive price manipulation where high barriers to entry exist, such that new, potentially competing firms are dissuaded from entering. Here, high barriers to entry have prevented entry by generic Clobetasol manufacturers despite the artificial inflation of pricing.

66. Companies seeking to manufacture and sell generic Clobetasol confront various significant barriers to entry.

67. High manufacturing and intellectual property costs, and increased regulatory oversight each represent substantial barriers to entry in the generic Clobetasol market. For example, while ANDAs are generally approved more quickly than NDAs, they still take more than a year to get approved and a majority of them are rejected.

3. Mutual Interchangeability of Defendants' Products

68. When products offered by different firms are viewed by purchasers as interchangeable, it is easier for the suppliers to agree on a single price of the product in question and it is easier to effectively monitor such prices. Thus, when a product is viewed as a "commodity" interchangeable with other products in the market, it is easier to form a cartel.

69. Generic drugs are interchangeable by definition. The generic Clobetasol manufactured by Defendants—while formulated differently in certain cases—are each chemical compounds composed of the same raw materials.

4. Inelastic Demand

70. If a given change in price triggers a smaller proportionate change in the quantity demanded, then the demand for the good or service is said to be inelastic. Where demand for a product is inelastic, increases in price result in limited declines in quantity sold or consumed in the market.

71. For a cartel to profit from raising prices above competitive levels, demand must be inelastic at competitive prices such that cartel members are able to raise prices without triggering a decline in demand that would make the concerted price increase unprofitable.

72. Generic Clobetasol is an important and medically necessary drug for millions of people. Patients consider it a medical necessity that must be purchased without regard to an increase in price. Generic Clobetasol is thus particularly susceptible to collusive price fixing as price increases will directly translate into more revenue for cartel members, rather than less.

5. Lack of Available Substitutes

73. While other dermatological drugs on the market seek to treat similar conditions, Clobetasol—a high strength topical corticosteroid—is often the only effective medicine for

patients. There are typically no available substitutes that afford patients the same level of efficacy as generic Clobetasol.

6. Absence of a Competitive Group of Sellers

74. Companies that are not part of the conspiracy can erode cartel members' market shares by offering products at lower, more competitive prices, which in turn erodes revenues. In the market for generic Clobetasol, there is no practical threat that a group of competitive sellers will take market share from Defendants. Defendants maintain oligopolistic power over the market for generic Clobetasol, which facilitates their ability to raise prices without the risk of losing market share to firms that are not members of the conspiracy.

7. Ease of Information Sharing Among Defendants

75. As described in paragraph 55 above, Defendants Hi-Tech, Perrigo, Taro U.S.A., Sandoz, and Wockhardt each are members of and attended the 2014 GPhA annual meeting immediately prior to implementing their Clobetasol price increases. The DOJ is analyzing trade associations like GPhA as a potential avenue for facilitating collusion between different generic manufacturers as part of its years-long investigation into anticompetitive pricing activities among generic manufacturers.

76. Because of their common membership in GPhA, there were opportunities both before and after the proposed Class Period for Defendants to collude by discussing competitive information regarding their generic Clobetasol products.

E. Current United States Antitrust Investigations Into Anticompetitive Practices in the Generic Pharmaceutical Industry

77. Several governmental investigations have been opened in response to dramatic price increases across the generic pharmaceutical industry. Multiple congressional investigations were launched, including investigations into Valeant Pharmaceutical International and Turing

Pharmaceuticals for their practice of raising prices on older generic drugs. Turing—which increased the price of life-saving drugs—was also the target of antitrust probes by the Federal Trade Commission and the New York attorney general. Recently, Mylan NV has been subject to congressional and regulatory scrutiny for raising the price of the Epipen, with the New York attorney general announcing investigation of potential antitrust violations connected to Mylan's contracts to provide the Epipen to schools.

78. According to a December 2015 report prepared by the Office of Inspector General for the United States Department of Health and Human Services, 22 percent of the top 200 generic drugs rose faster than the price of inflation between 2005 and 2014.

79. In April 2015 the Department of Health and Human Services Inspector General undertook an investigation into the sudden price increases implemented by generic drug manufacturers.

80. In 2014 testimony before the Subcommittee on Primary Health and Aging, pharmaceutical industry experts affirmed (1) the importance of generic drugs to the American people as an access vehicle to drugs many people wouldn't be able to otherwise afford; and (2) that generic drug prices were not following traditional pricing patterns and were instead undergoing substantial increases.

81. Over the last year, the DOJ has issued subpoenas to a number of generic drug manufacturers including Actavis Plc (now Allergan Plc), Endo International Plc, Lannett Co. Inc., Par Pharmaceutical Holdings Inc., Impax Laboratories Inc., and Mylan N.V. to investigate anticompetitive practices in the generic pharmaceutical industry.

82. On September 9, 2016, Defendant Taro Israel disclosed that on September 8, 2016, Defendant Taro U.S.A “as well as two senior officers in its commercial team, received

grand jury subpoenas from the United States Department of Justice, Antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and pricing, communications with competitors and others regarding the sale of generic pharmaceutical products, and certain other related matters.”

VIII. EFFECTS ON COMPETITION, AND DAMAGES

83. Defendants’ combination and conspiracy as set forth in this complaint has had the following effects, among others:

- Competition in the market for generic Clobetasol has been reduced;
- Prices for generic Clobetasol have increased, and run contrary to the typical pricing patterns of generic drugs over time;
- United States purchasers have been deprived of the benefit of free and open competition on the basis of price in the market for generic Clobetasol; and
- As a direct and proximate result of Defendants’ anticompetitive and unlawful conduct, Plaintiff and the Class of end-payors have been injured in their business and property in that, during the Class Period, they paid artificially inflated prices for generic Clobetasol.

84. Plaintiff and the Class have been damaged as measured by the full amount of the overcharges that they paid in an amount subject to proof and to be determined at trial.

85. The foregoing allegations are likely to have evidentiary support after a reasonable opportunity for discovery.

IX. ANTITRUST IMPACT

86. Supracompetitive prices at a higher level of distribution generally result in higher prices at every level below. Such is the case here.

87. Wholesalers and retailers passed on the supracompetitive prices of generic Clobetasol to Plaintiff and the Class.

88. Defendants' anticompetitive conduct enabled them to raise, fix, and stabilize prices to consumers and third-party payors in excess of the prices Defendants otherwise would have been able to charge absent their anticompetitive conduct.

89. The supracompetitive prices paid by Plaintiff and the Class are traceable to, and the direct, proximate, and foreseeable result of, Defendants' supracompetitive prices.

X. CLAIMS FOR RELIEF

CLAIM I
Violation of Section 1 of the Sherman Act, 15 U.S.C. § 1
(Asserted against all Defendants)

90. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

91. This claim is pled as to all Defendants.

92. Beginning at least as early as June 3, 2014, the exact date being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants entered into a continuing combination or conspiracy to unreasonably restrain trade and commerce in violation of section 1 of the Sherman Act, 15 U.S.C. § 1, by artificially reducing or eliminating competition for the pricing of generic Clobetasol in the United States.

93. In particular, Defendants have combined and conspired to raise, fix, maintain or stabilize the prices of generic Clobetasol in the United States during the Class Period.

94. As a result of Defendants' and their co-conspirators' unlawful conduct and acts taken in furtherance of their conspiracy, prices for generic Clobetasol sold to purchasers in the United States during the Class Period were raised, fixed, maintained or stabilized at artificially inflated levels.

95. The combination or conspiracy among Defendants consisted of a continuing agreement, understanding and concerted action among Defendants and their co-conspirators.

96. For purposes of formulating and effectuating their combination or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix, raise, maintain, and/or stabilize the prices of generic Clobetasol, including: (1) participating in meetings to discuss their respective generic Clobetasol prices and how they could coordinate their actions to restrain trade for their generic drug products; (2) agreeing to coordinate and manipulate the prices and available supply of generic Clobetasol in a manner that deprived United States purchasers of free and open price competition; and (3) providing pretextual justifications to purchasers and the public to explain any raises, maintenance or stabilization of the prices for Defendants' generic Clobetasol.

97. Defendants' anticompetitive and unlawful conduct is illegal *per se*.

98. As a direct and proximate result of Defendants' anticompetitive and unlawful conduct, Plaintiff and the Class of end-payors have been injured in their business and property in that they have paid more for the generic Clobetasol that they purchased during the Class Period than they otherwise would have paid absent Defendants' wrongful conduct.

CLAIM II
Violation of Section 3 of the Sherman Act, 15 U.S.C. § 3
(Asserted against all Defendants)

99. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

100. This claim is pled as to all Defendants.

101. Beginning at least as early as June 3, 2014, the exact date being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants entered

into a continuing combination or conspiracy to unreasonably restrain trade and commerce in violation of section 3 of the Sherman Act, 15 U.S.C. § 3, by artificially reducing or eliminating competition for the pricing of generic Clobetasol in any territory of the United States or in the District of Columbia.

102. In particular, Defendants have combined and conspired to raise, fix, maintain or stabilize the prices of generic Clobetasol in any territory of the United States or in the District of Columbia during the Class Period.

103. As a result of Defendants' and their co-conspirators' unlawful conduct and acts taken in furtherance of their conspiracy, prices for generic Clobetasol sold to purchasers in any territory of the United States or in the District of Columbia during the Class Period were raised, fixed, maintained or stabilized at artificially inflated levels.

104. The combination or conspiracy among Defendants consisted of a continuing agreement, understanding and concerted action among Defendants and their co-conspirators.

105. For purposes of formulating and effectuating their combination or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix, raise, maintain, and/or stabilize the prices of generic Clobetasol, including: (1) participating in meetings to discuss their respective generic Clobetasol prices and how they could coordinate their actions to restrain trade for their generic drug products; (2) agreeing to coordinate and manipulate the prices and available supply of generic Clobetasol in a manner that deprived United States purchasers of free and open price competition; and (3) providing pretextual justifications to purchasers and the public to explain any raises, maintenance or stabilization of the prices for Defendants' generic Clobetasol.

106. Defendants' anticompetitive and unlawful conduct is illegal *per se*.

107. As a direct and proximate result of Defendants' anticompetitive and unlawful conduct, Plaintiff and the Class of end-payors have been injured in their business and property in that they have paid more for the generic Clobetasol that they purchased during the Class Period than they otherwise would have paid absent Defendants' wrongful conduct.

CLAIM III
Conspiracy and Combination in Restraint of Trade Under State Law
(Asserted against all Defendants)

108. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

109. This claim is pled as to all Defendants.

110. Beginning at least as early as June 3, 2014, the exact date being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants entered into a continuing combination, conspiracy or agreement to unreasonably restrain trade and commerce in restraint of trade, the purpose and effect of which was to fix, raise, maintain or stabilize the price of generic Clobetasol.

111. Defendants implemented the terms of their combination, conspiracy, or agreement and achieved their intended purpose. As a direct and proximate result of Defendants' anticompetitive conduct, as alleged herein, Plaintiff and the Class were harmed as set forth above.

112. Defendants' unlawful combination, conspiracy or agreement harmed competition in the market for generic Clobetasol.

113. There was and is no legitimate, non-pretextual, procompetitive justification for Defendants' dramatic, coordinated price increases that outweigh the increases' harmful effect.

Even if there were some conceivable justification, the price increase were not necessary to achieve that purpose.

114. By engaging in the foregoing conduct, Defendants entered a conspiracy and combination in restraint of trade in violation of the following state laws:

- Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases in Arizona by members of the Class and/or purchases by Arizona residents.
- Cal. Bus. And Prof. Code §§ 16720, *et seq.*, with respect to purchases in California by members of the Class and/or purchases by California residents.
- D.C. Code § 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Class and/or purchases by District of Columbia residents.
- Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class and/or purchases by Florida residents.
- Haw. Rev. Stat. § 480-1, *et seq.*, with respect to purchases in Hawaii by members of the Class and/or purchases by Hawaii residents.
- Iowa Code § 553.1, *et seq.*, with respect to purchases in Iowa by members of the Class and/or purchases by Iowa residents.
- Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class and/or purchases by Kansas residents.
- Me. Rev. Stat. Ann. 10 § 1101, *et seq.*, with respect to purchases in Maine by members of the Class and/or purchases by Maine residents.
- Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class and/or purchases by Massachusetts end-payors paying substantially higher prices for generic Clobetasol in actions and transactions occurring substantially within Massachusetts.
- Mich. Comp. Laws § 445.771, *et seq.*, with respect to purchases in Michigan by members of the Class and/or purchases by Michigan residents.
- Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases in Minnesota by members of the Class and/or purchases by Minnesota residents.
- Miss. Code § 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class and/or purchases by Mississippi residents.

- Neb. Rev. Stat. § 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class and/or purchases by Nebraska residents.
- Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class and/or purchases by Nevada residents, in that thousands of sales of generic Clobetasol occurred at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to purchases in New Hampshire by members of the Class and/or purchases by New Hampshire residents.
- N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class and/or purchases by New Mexico residents.
- New York General Business law § 340, *et seq.*, with respect to purchases in New York by members of the Class and/or purchases by New York residents.
- N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class and/or purchases by North Carolina residents.
- N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases in North Carolina by members of the Class and/or purchases by North Dakota residents.
- S.D. Codified Laws Ann. § 37-1-3.1, *et seq.*, with respect to purchases in South Dakota by members of the Class and/or purchases by South Dakota residents.
- Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class and/or purchases by Tennessee residents, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for generic Clobetasol at Tennessee pharmacies.
- W. Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Class and/or purchases by West Virginia residents.
- Wis. Stat. § 133.03, *et seq.*, with respect to purchases of generic Clobetasol in Wisconsin by members of the Class and/or purchases by Wisconsin residents, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for generic Clobetasol at Wisconsin pharmacies.

115. Plaintiff and members of the Class have been and will continue to be injured in their business or property by reason of Defendants' violations of the laws set forth above, in that

Plaintiff and Class members (i) were denied the opportunity to purchase lower-priced generic Clobetasol, and (ii) paid higher prices for generic Clobetasol than they would have paid but for Defendants' unlawful conduct. Such injuries are of the type the laws of the above-listed jurisdictions were designed to prevent and flow from that which makes the conduct complained of unlawful.

116. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries.

CLAIM IV
Violation of State Consumer Protection Statutes
(Asserted against all Defendants)

117. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

118. This claim is pled as to all Defendants.

119. Beginning at least as early as June 3, 2014, the exact date being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants engaged in unfair competition or unfair and/or unconscionable acts or practices with respect to the sale of generic Clobetasol in violation of the following state consumer protection and unfair competition statutes:

- D.C. Code Ann. §28-3901, *et seq.*;
- Fla. Stat. §§ 501.201, *et seq.*;
- Haw. Rev. Stat. § 480-2, *et seq.*;
- Kan. Stat. Ann. §§ 50-623, *et seq.*;
- Mass. Gen. Laws chapter 93A §§ 1, *et seq.*;
- Mich. Comp. Laws § 445.901, *et seq.*;

- Miss. Code §§ 75-24-1, *et seq.*;
- Neb. Rev. Stat. §§ 59-1601, *et seq.*;
- N.H. Rev. Stat. Ann. §§ 358-A:1, *et seq.*;
- N.M. Stat. Ann. §§ 57-12-1, *et seq.*;
- N.C. Gen. Stat. §§ 75-1.1, *et seq.*; and
- Rhode Island Gen. Laws §§ 6-13.1-1, *et seq.*

120. Defendants agreed to, and did, act in restraint of commerce by affecting, fixing, controlling and/or maintaining, at artificial and non-competitive levels, the prices at which generic Clobetasol was sold, distributed, or obtained and took efforts to conceal their agreements from plaintiff and the Class.

121. Defendants' intentional and purposeful anti-competitive acts, described above, were intended to and did cause Plaintiff and Class members to pay supracompetitive, artificially inflated prices for the generic Clobetasol they purchased in the states listed above.

122. As a direct and proximate result of the Defendants' unlawful conduct, Plaintiff and the Class have been injured in their business and property in that they paid more for generic Clobetasol than they otherwise would have paid in the absence of Defendants' unlawful conduct.

123. Plaintiff and the Class are therefore entitled to all appropriate relief as provided for by the laws of the states listed above, including but not limited to, actual damages, injunctive relief, attorneys' fees, and equitable relief, such as restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits which may have been obtained by Defendants as a result of their unlawful conduct.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully requests that the Court:

- A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a), (b)(2), and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and declare the Plaintiff as the representative of the Class;
- B. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Class;
- C. Award the Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;
- D. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' illegal conduct, including:
 - i. A judicial determination declaring the rights of Plaintiff and Class members and the corresponding responsibilities of Defendants;
 - ii. A declaration that Defendants are to be financially responsible for the costs and expenses of a Court-approved notice program by mail, broadcast media, and publication designed to give immediate notification to Class members;
 - iii. Disgorgement and/or the imposition of a constructive trust upon Defendants' ill-gotten gains, thereby freezing Defendants' assets, and/or requiring Defendants to pay restitution to Plaintiff and all members of the Class of all funds acquired by any means of any act or practice declared by this Court to be an unlawful or unfair business practice, a violation of federal or state statutes, or to constitute unfair competition; and
- E. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law.

XII. DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff, on behalf of itself and the proposed Class demands a trial by jury on all issues so triable.

Dated: September 15, 2016

Respectfully Submitted

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